EPA Jacket 100-902
Vol.3

syngenta

Carolyn F. Brinkley
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Regulatory Affairs
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Federal Express

December 2, 2012

Document Processing Desk (DCI/PRD)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Katherine St. Clair – Pesticide Re-evaluation Division

SUBJECT: EMAMECTIN BENZOATE REGISTRATION REVIEW

Case No. 7607
Docket ID No. EPA-HQ-OPP-2011-0483

Proposal that EPA discontinue use of emamectin benzoate studies with CF-1 mouse for human health risk assessment--written submission of Nov. 2011 presentation to PRD/RD/HED

Dear Sir or Madam:

Syngenta Crop Protection, LLC is submitting information that will be applicable to the Agency's human health risk assessment which will be conducted as part of the Registration Review of emamectin benzoate (hereafter emamectin).

Since the EPA registered the first use of emamectin and, to date, the EPA has used a 15-day neurotoxicity study with emamectin in the CF-1 mouse for the value that is used to assess the human health risk associated with exposure to emamectin.. In 1998 Syngenta (Novartis) submitted a document to the EPA which was intended to support the position that the CF-1 mouse was not the appropriate species for the assessment of human risk associated with exposure to emamectin. The EPA had already reviewed a comparable submission regarding the use of the CF-1 mouse for assessing human risk associated with exposure to abamectin and the Agency concluded that the CF-1 mouse was not the appropriate species for human health risk assessment. In a document dated June 24, 2003, the HIARAC responded to Novartis' argument that the CF-1 mouse was not appropriate for assessing the risk of human exposure to emamectin. In this document, the HIARAC indicated that:

> *"the endpoints [for emamectin] would be reconsidered provided the registrant submits a special study that demonstrates a clear relationship between neurotoxicity and P-glycoprotein deficiency in genotyped CF-1 mice"*

In November 2011 Syngenta met with EPA (RD,PRD, & HED) to present new information that demonstrated a clear relationship between neurotoxicity and p-glycoprotein deficiency in CF-1 mice exposed to emamectin. Following that meeting, Tom Harrison, Registration Division, stated in an e-mail message:

> "We discussed the emamectin CF-1 issue after your presentation and decided that it would not affect the current PRIA actions (cucurbits group 9, ornamentals). Therefore, we will not make a formal decision under these two PRIA deadlines. Instead, the registration review draft work plan will go forward with HED's current requirement for chronic inhalation using the CF-1 mouse, Syngenta can formally respond to PRD with your discount the CF-1 mouse rebuttal, and OPP will review the rebuttal and make a determination during reg review."

As I have discussed with Tom Harris and Katherine St. Clair Syngenta is submitting our written proposal (rationale) that the EPA discontinue use of any emamectin studies with the CF-1 mouse to assess human health risk associated with exposure to emamectin. In addition to this rationale, we are also submitting 2 studies that are referenced in the rationale.

The November 2012 DCI for emamectin notes that a 90-day inhalation study is required. It is our understanding from other EPA correspondence that this study is supposed to conducted with the CF-1 mouse. As discussed in the accompanying rationale, Syngenta is presenting information that indicates the CF-1 mouse is not an appropriate strain to use in studies for human health risk assessment. Therefore, Syngenta is planning to submit its proposal, for EPA approval, to conduct a 28-day inhalation study with emamectin in the rat instead.

If you have any questions about this submission, please contact me. I can be reached at 336 632 2838

Sincerely,

Carolyn F. Brinkley

Carolyn F. Brinkley
Sr. Regulatory Product Manager / NAFTA Insecticides
Regulatory Affairs

Enclosures: Transmittal Document, Rationale, Two tox studies

Material to be added to an e-Jacket/Jacket

Reg. # _____ Decision # _____

Description: FYI – old method validation review 7-17-2003 re: livestock 7F4845

1. Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top = newest)
   - ☐ File Location: (eg. "before page 45 in .pdf")

     _____

2. ☐ Send to Data Extraction contractors this material:
   - ☐ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: _____

Created December 6, 2010

Fw: emamectin benzoate method validation memo dated 7/17/03

Nancy Dodd to: Thomas Harris 02/24/2011 05:37 PM

For your information, this resolves the livestock method issue.

----- Forwarded by Nancy Dodd/DC/USEPA/US on 02/24/2011 05:35 PM -----

From: Charles Stafford/DC/USEPA/US
To: Nancy Dodd/DC/USEPA/US@EPA
Date: 02/24/2011 04:58 PM
Subject: Re: emamectin benzoate method validation memo dated 7/17/03

Here is a scan of our hard copy:

B02-(25-29), ACB review memo, emamectin livestock.pdf

~~~~~~~~~~~~~~~~~~~~~~~~

Charles J. Stafford
EPA Office of Pesticide Programs
EPA Environmental Science Center
Analytical Chemistry Laboratory
701 Mapes Road
Fort Meade, Maryland 20755-5350
(410) 305-2914
stafford.charles@epa.gov

Nancy Dodd I am looking for an ACB/BEAD method validatio... 02/24/2011 12:52:16 PM

From: Nancy Dodd/DC/USEPA/US
To: Charles Stafford/DC/USEPA/US@EPA
Date: 02/24/2011 12:52 PM
Subject: emamectin benzoate method validation memo dated 7/17/03

I am looking for an ACB/BEAD method validation memo for emamectin benzoate on livestock commodities, identified as for PP#7F4845, written by E. Kolbe, dated 7/17/03. Can you find it in BEAD files?
~~~~~~~~~~~~~~~~~~~~~~~~

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Analytical Chemistry Branch
Environmental Science Center
Fort George G. Meade, Maryland 20755-5350

OFFICE OF
PESTICIDE PROGRAMS

17 July 2003

MEMORANDUM

SUBJECT: PP#7F4845. Emamectin Benzoate on Livestock Commodities
Tolerance Method Review
PC Code 122806 (MRID#:448837-12 and 448837-13)(Barcode#:D2880045)
B02-(25-29).

FROM: Elizabeth J. Kolbe, Chemist
Analytical Chemistry Branch

THRU: Charles J. Stafford, Acting Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (7503C)

TO: Paula Deschamp, Chief
Registration Action Branch 3
Health Effects Division (7509C)

And

Marion Johnson, Chief
Insecticide Branch
Registration Division (7505C)

INTRODUCTION

The Analytical Chemistry Branch (ACB) was requested by the Registration Action Branch 3 (RAB-3) to conduct a tolerance method validation of the proposed enforcement method submitted by Syngenta Crop Protection, Inc. (formerly Novartis) for the determination of residues of the insecticide emamectin benzoate and its primary metabolite on/in milk, beef fat, kidney, liver and meat.

The ACB has reviewed the following analytical methods, data and reports:

1. Residue Analytical Method, MRID # 448837-12: "Method Validation of the HPLC-Fluorescence Method to Determine Residues of MK-0244 and its 8,9-Z Isomer in Bovine Tissues, Milk, and Plasma", dated 5/30/97, by T. Wehner and L. Morneweck; Novartis No. 1031-99.

2. Independent Laboratory Validation Data, MRID # 448837-13: "Independent Laboratory Validation for the Determination of Emamectin Benzoate (MK-0244) Residues in Bovine Liver Tissue and Milk", dated 9/19/97, by V. Kvaternick, Analytical Development Corporation, Colorado Springs, CO, Novartis No. 1033-99.

3. The HED Residue Chemistry Review; Memorandum, dated 2/19/02, M. Xue, (d267346.mem.wpd).

4. The ACB Tolerance Method Validation Report, Plant Method; Memorandum, dated 6/16/99, E. Kolbe.

RECOMMENDATIONS:

The ACB recommends OPP acceptance of the petitioner's Residue Analytical Method data without an ACB laboratory validation based on the following conclusions:

COMMENTS AND CONCLUSIONS:

1) The ACB finds that the method meets the requirements of Residue Chemistry Test Guideline 860.1340 to enforce tolerances. The method as written contains no major deficiencies. The ACB concludes that Agency laboratory validation of this method is not necessary at this time.

2) The petitioner has provided evidence of a successful ILV. The independent lab found no significant method deficiencies during the ILV.

3) ACB previously successfully validated a plant method (MRID # 428689-04) for emamectin and its metabolite (ACB Project # B99-(20-21), ACB TMV Report Memo dated 6/16/99 by E. Kolbe). That method used similar methodology and instrumentation.

4) The ACB will forward this animal commodity method to the Food and Drug Administration for publication in a future edition of PAM 2, and will include the method in BEAD's Residue Analytical Methods Index for distribution through the internet.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

COPY
file in technical 100-902

MEMORANDUM

Date: January 28, 2009

SUBJECT: **Revised.** Emamectin Benzoate; Change of WPS REI from 48 to 12 Hours. Review of Supporting Rationale.

PC Code: 122806
Decision No.: 389854 and 390649
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D360697 and D360698
Registration No.: 100-903 and 100-904
Regulatory Action: Label Change
Case No.: NA
CAS No.: NA
40 CFR: NA

FROM: Jack Arthur, Environmental Scientist
Registration Action Branch 3 (RAB3)
Health Effects Division (7509P)

THROUGH: Paula Deschamp, Chief RAB3
Health Effects Division (7509P)

TO: Thomas Harris, Risk Manager
Insecticide Branch
Registration Division (7505P)

Introduction

This revised memorandum supersedes the previous version (DP#s: 350218 and 350219, May 7, 2008) in its entirety.

Two currently registered emamectin benzoate products, Denim® (EPA Reg. No. 100-903) and Proclaim® (EPA Reg. No. 100-904) are labeled with a Worker Protection Standard (WPS) Restricted Entry Interval (REI) of 48 hours based on a Category I for eye irritation resulting from the acute six-pack conducted on the technical product, Emamectin Benzoate Technical (EPA Reg. No. 100-902). In December of 2007, OPP registered a new technical emamectin benzoate, called Emamectin Benzoate Technical II (EPA Reg. No. 100-1207), which is produced by a new manufacturing company. The registrant is Syngenta Crop Protection Inc. The acute six-pack of tests performed on this new technical product resulted in new toxicity category assignments.

Specifically, the toxicity category for inhalation changed from Category IV to Category II. Relevant to the REI, the eye irritation study changed from Category I to Category III. Toxicity categories for dermal toxicity, skin irritation and eye irritation are all at least Category III, and therefore, the resulting WPS REI for products made from this new technical will be 12 hours. The original technical product registration is to be cancelled and all new production of Denim® and Proclaim® is to be made with the new technical product Emamectin Benzoate Technical II, produced by a new manufacturer.

RD has asked HED to comment on the REI change and if there are any other factors besides the acute toxicity profile that would **prevent** a 12 hour REI.

Discussion

Byron Backus, a toxicologist with the Technical Review Branch of the Registration Division, reviewed the acute toxicity studies for the new technical product, Emamectin Benzoate II (DP#: 335160; August 14, 2007). Indira Gairola, with the same group, reviewed the product chemistry (DP# 335159; August 7, 2007).

Indira Gairola, based on a review of the product chemistry, concluded that the Emamectin Benzoate Technical II is similar to the previous technical product, especially in regard to the impurity profile.

Dr. Backus concluded, based particularly on the acute toxicity profiles, that it had not been established that the new technical and the previous technical materials are substantially similar. He addressed the differences in the acute inhalation toxicity category, but did not address the differences in the primary eye irritation category, which is the relevant one for REI determinations.

The following table includes lists of the Toxicity Categories for the new and previous technical products for comparison purposes.

Study Type	Tox Category (new technical)	Study Acceptibility	MRID No.	Tox. Category (previous technical)
Acute oral	II	Acceptable	47002104	II
Acute dermal	III	Acceptable	47002106	III
Acute inhalation	II	Acceptable	47002107	IV
Primary eye irritation	III	Acceptable	47002108	I
Primary dermal irritation	IV	Acceptable	47002109	IV
Dermal sensitization	Negative	Supplementary	47002110	Negative

Gerome Burke, toxicologist in the Health Effects Division reviewed the acute toxicity profiles and product chemistries of the new and previous technical products (DP# 335161; September 27, 2007) and concluded that Emamectin Benzoate Technical II and Emamectin Benzoate Technical are chemically and toxicologically similar based on chemistry and toxicity characterization. He concluded that two impurities identified in the new technical product are not of toxicological relevance based on structure and toxicity data collected. Dr. Burke addressed the difference in eye irritation Toxicity Categories between the previous technical product (Category I) and the new product (Category III) as possibly being due to small differences in methodology. Dr.

Backus indicated in a personal discussion (04/30/08) that the use of an anesthetic in the new study and the use of a more finely ground technical product in the original study, are examples of methodological factors that could result in differences in study outcome.

Conclusion

No study irregularities or problems were documented in the reviews conducted by Drs. Backus and Burke on the six-pack acute studies for the new Emamectin Benzoate II. In previous HED assessments, the risks to workers (based on systemic toxic effects of emamectin benzoate) who re-enter treated fields on the day of treatment did not concern HED for all relevant agricultural activities **except** thinning (pome fruits) and poling, thinning, pruning and hand-harvesting nut trees. The latter activities must wait 2 days following application before the risks do not exceed HED's level of concern.

In conclusion, from assessments on existing agricultural use sites, a comparison of relevant systemic toxic effects with estimated exposure from postapplication activities does not result in estimates of risk that would prevent a 12 hour REI for most activities except thinning pome fruit trees and hand-harvesting, pruning, thinning and poling nut trees; these latter specific crop activities requiring a 2-day REI..

While checks of Poison Control Center (1993 – 2005) and IDS (2000 – present) Data Bases were negative, in any future risk assessments for emamectin benzoate, a check for eye irritation incidents should be repeated by HED.

Recommendations

HED has concern for the possibility that a change in manufacturers and technical registrations can result in a different (in the case of emamectin benzoate eye irritation, a more favorable) acute toxicity outcome, while the technical compound itself has not changed. HED notes the severe neurotoxicity of emamectin benzoate. While emamectin benzoate neurotoxicity may not be specifically relevant to this subject request for an REI reduction, it influences HED's concern for any lessoning of mitigation.

HED acknowledges that a new six-pack of acute tests also may result in a more hazardous toxicity category (e.g., as happened with the emamectin benzoate acute inhalation toxicity category). But in either event, HED believes that such changes should be accompanied by detailed confirmational information. Such information should be obtained before allowing the current request for an REI reduction, and before allowing any such future requests. Specifically, **HED recommends that the registrant describe the reasons (e.g., differences in labs or test methodology) that could account for the difference in acute eye irritation study results (i.e., a major change from Category I to Category III).**

Material to be added to an e-Jacket/Jacket

Reg. No. 100-902

Transmittal of 28-day inhale protocol

1. ☒ **Placement within the e-Jacket/jacket:**
   - ☒ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

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2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Tom Harris

Phone: 308 9423 **Division:** RD

Date: 10/27/08

Created July 21/2008

Thomas
Harris/DC/USEPA/US
10/27/2008 11:51 AM

To carolyn.brinkley@syngenta.com
cc
bcc
Subject emamectin: review 28-day inhale protocol

Carolyn,

I just picked up the attached review from HED. This is an old topic and I think you're already aware of the answer. You had come in 9/06 to discuss the protocol for a 28-day inhalation study for emamectin and followed up with some additional material 10/06. I sent it to HED. This is their formal response.

This email will be the official transmission of this review; I will not follow-up with a paper mailing.

emamectin.20081023.28-day inhale protocol.EPA review.image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDE AND TOXIC SUBSTANCES

MEMORANDUM

Date: 10/23/2008

SUBJECT: Emamectin benzoate: Response to registrant's request regarding a protocol for a 28-day inhalation toxicity study.

PC Code: 122806
Decision No.: 371487
Petition No.: N/A
Risk Assessment Type: N/A
TXR No.: 0055024
MRID No.: N/A

DP Barcode: d333348
Registration No.: N/A
Regulatory Action: N/A
Case No.: N/A
CAS No.: N/A
40 CFR: N/A

FROM: Whang Phang, PhD
Toxicologist
RAB3/HED (7509P)

THROUGH: Paula Deschamp, Branch Chief
RAB3/HED (7509P)

TO: Thomas Harris
Risk Manager Reviewer
IRB/RD (7505P)
And
Nancy Dodd, Risk Assessor
RAB3/HED (7509P)

CONCLUSION: RAB3 recommends that the registrant conduct the 28-day inhalation toxicity study using CF-1 P-glycoprotein [mdr 1a](-/-) mice.

ACTION REQUESTED: RAB3 is requested to comment on a study protocol for a 28-day inhalation toxicity study on emamectin, specifically the species of mice to be tested.

DISCUSSION: On September 13, 2006, Kathleen Raffaele (formerly of RAB3) and other HED toxocologists, met with representatives of Syngenta Crop Protection Inc. to discuss test parameters of a 28-day inhalation toxicity study with emamectin benzoate. Based on evaluation of additional information supplied by Syngenta in their letter dated October 18, 2006 as well as evaluation of

available literature regarding the role of P-glycoprotein in the toxicity of emamectin, HED/RAB3 concludes that there is sufficient evidence of genetic polymorphism in the human population for this gene/protein to raise concern about the existence of a sensitive human population. Recent reports indicate human genetic polymorphism, including negative homozygotes, for this gene have been detected, some of which result in a dysfunctioning transporter protein. The existence of a sensitive human population would also be consistence with the well-documented sensitive population in several other species of mammals, such as collie dogs, CF-1 mice, and cows.

In addition, the registrant, Syngenta, stated in its submission that approximately 98% of the human population carry at least one copy of P-glycoprotein haplotyes that have been shown to produce functional P-glycoprotein in the blood brain barrier. It is then plausible that approximately 2% of the human population may have dysfunctional P-glycoprotein the blood brain barrier and other tissues where P-glycoprotein is also located. In considering this possibility relative to the US population, which consists of approximately 300 million individuals, 2% of 300 million is 6 million individuals. This is not a small number of individuals who may have dysfunctional P-glycoprotein. Based on this evaluation, HED/RAB3 concludes that it is most appropriate to use the similarly sensitive mouse strain (CF-1 homozygous mdr 1a (-/-)) in the 28-day inhalation toxicity study.

MATERIAL TO BE ADDED TO JACKET

REG # 100-902

Description: transmittal of old DERs

if applicable, check all that are attached

- ☐ new stamped accepted label
- ☐ new CSF
- ☐ notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Tom Harris Date: 7/15/08

Phone: 308-9423 Division: RD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

7/15/2008

Carolyn Brinkley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: emamectin: copies of old DERs

Dear Ms. Brinkley:

Enclosed please find a paper copy of the data evaluation reports (DERs) for the following MRIDs concerning emamectin along with a new cover memo (6/5/08). Also enclosed is a copy of the 6/30/98 risk assessment (6/30/98) which used these studies.

438501-11
438681-03
440079-02
438681-05
438681-04
440306-01
438501-13

These studies are associated with one of the original uses of emamectin. HED was recently checking their files and noticed that they had never officially transmitted the DERs for these studies to RD (and hence they may not have been sent to you). We've exchanged emails over the past two months concerning these and other old emamectin DERs. You've already emailed me a few DERs that we were missing; the enclosed copies are to fill in any blanks in your records, if needed.

Sincerely yours,

/s/

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505C)
Harris.Thomas@epa.gov
(703) 308-9423

enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: June 5, 2008

SUBJECT: Emamectin: Transmission of 7 toxicity DERs

PC Code: 122806
Decision No.: 384481
Petition No.NA:
Risk Assessment Type: NA
TXR No.: 0054867
MRID No.: see table below

DP Barcode: D353280
Registration No.: NA
Regulatory Action: New Use
Case No.: NA
CAS No.: 155569-91-8
40 CFR: NA

Ver.Apr.08

FROM: Marion Copley, DVM, DABT Marion Copley 6/5/08
Science Information Management Branch
Health Effects Division (7509P)

THROUGH: Jessica Kidwell Jessica Kidwell 6/5/08
Science Information Management Branch
Health Effects Division (7509P)

TO: Thomas Harris/John Hebert (RM 07)
Insecticide Rodenticide Branch
Registration Division (7505P)

CC: Nancy Dodd (RAB3), Whang Phang (RRB1)

I. CONCLUSIONS

The Data Evaluation Records (DERS) for 7 studies (MRIDs 43850111, 43868103, 44007902, 43868105, 43868104, 44030601, 43850113) are attached.

II. ACTION REQUESTED

Complete the purple folder process for 7 DERs that have not been officially sent out of HED.

III. BACKGROUND

These 7 DERs were completed in 1996 and 1997 for the registration process of Emamectin. They were evaluated by the TOX-SAC (report signed 02/05/98) by Joycelyn Stewart. A memorandum (TXR 012650) was sent out of HED on 06/30/98 stating that these DERs were

attached. However, there is no record that they were actually attached to the memorandum. They were not available in the Archives, the old OneLiners (stand alone Access version) or the IHAD databases.

IV. MRID Summary Table

Study Type	MRID	Comments
(82-1) Acute dermal (neurotoxicity part) -rat	43850111	New DER
(82-1) Subchronic (gavage) oral toxicity - dogs	43868103	New DER
(82-2) Repeated dose dermal – rabbit	44007902	New DER
(83-2) Oncogenicity - mouse	43868105	New DER
(83-5) Chronic/oncogenicity – rat	43868104	New DER
(85-1) Metabolism – rat	44030601	New DER
(85-2) Dermal absorption - rat	43850113	New DER

13544

001481

Chemical:	**4''-Epimethylamino-4''-deoxyavermectin B**
PC Code:	**122806**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**06/30/1998**
File ID:	**TX012650**
Accession Number:	**412-01-0082**

HED Records Reference Center
01/10/2001

MICROFICHE

B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

012650

JUN 30 1998

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA ID#: 000618-RNI: Application for Establishment of Permanent Tolerance for the use of Emamectin on Cole Crops and Leafy Vegetables

DP CODE Nos.: D226267 & D233451
Submission #s: S501714 & S507199
P.C.#: 122806

From: Guruva B. Reddy, D.V.M., Ph. D.
Reregistration Branch II
Health Effects Division (7509C)

William G. Dykstra, Ph.D., D.A.B.T
Registration Branch I
Health Effects Division (7509C)

To: Donna Davis
Registration Branch II
Health Effects Division (7509C)

Thru: Alan P. Nielson, Ph.D.
Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

Melba S. Morrow, D.V.M.
Branch Senior Scientist
Registration Branch I
Health Effects Division (7509C)

cc: George Larocca/Linda Arrington
Project Manager 13
Registration Division (7505C)

I. CONCLUSIONS:

The data base supports the establishment of permanent tolerance for the use of emamectin for the control of insects on cole crops and leafy vegetables.

A copy of the DERs are attached.